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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,456	09/30/2003	Ralph N. Martins	520531-2001	5975

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
05/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,456	MARTINS, RALPH N.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-36,38 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-36,38 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 2/23/09 has been entered.

2. The rejection of claims 27-36 & 47 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn because the claims recite both definable structural and functional characteristics to enable at least one embodiment of the instantly claimed invention (e.g., as it especially relates to claim 47).

3. Applicant's arguments filed 2/23/09 have been fully considered but they are not deemed to be fully persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 27-36, 38 & 47 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 20081218. **This is a new matter rejection**.

Applicants argue that they have amended the claims to now recite "copper binding", etc. Therefore, this part of the new matter rejection (i.e., as it relates to limitations originally submitted 9/10/07) is obviated.

However, Applicants did not address the new matter rejection related to the recitation of "which is ***at least 6 amino acids*** *in length and which is at least 80% identical* to the recited sequence". Again, mixing and matching different concepts of fragments and % identity still alternatively broaden the scope of that contemplated at the time of filing the instant specification. As was previously made of record, for example, contemplation of 80% identity to a 15 a.a. peptide (i.e., SEQ ID NO: 3) encompasses a 12 amino acid fragment of SEQ ID NO: 3, not a peptide "6 amino acids in length", which alternatively constitutes only 40% identity (i.e., 6/15). Thus, no contemplation related to this broader scope claimed (e.g., 40% identical versus 80% identical) exists in the specification as originally filed; thereby, still constituting new matter.

It is again noted that the rejection under 35 U.S.C. 102(b), as being anticipated by Wakasugi et al (1994) was previously withdrawn solely due to the amendment of the claims to "a functional variant thereof which is *at least 6 amino acids*…". It is noted that this rejection may be re-instated should Applicants choose to amend the claims to overcome this new matter rejection.

6. Claims 27-36, 38 & 47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention, for the reasons made of record in Paper No: 20071130 & 20081218, and as follows. **This is a written description rejection**.

Applicants argue on pages 4-5 of the response that "for the two 6 amino acid sequences (SEQ ID NO: 1 and SEQ ID NO: 2), the functional variants will have at least 6 amino acids, but there may be type substitutions such as modified or different amino acids within the sequence". A similar argument is made for changing or deleting any amino acid as depicted in SEQ ID NO: 3, as long as the peptide is "at least 6 amino acids in length". In other words, as previously made of record, there is no identification of any particular portion of the structure that must be conserved, and therefore, it appears Applicant is arguing that not a single definable/specific amino acid as depicted in SEQ ID NO: 1 or 2 or 3 is required for binding to Aβ or to inhibit SOD activity or copper binding ability, in order to show even a minimum correlation between structure and the recited functional language. This does not address the written description rejection of record, and still does not reasonably demonstrate possession of a representative number of the 80% sequence identity genus claimed. Likewise, not a single "nonpeptide peptiomimetic" (i.e., as it relates to claim 38) is described within the instant specification, which Applicants also failed to address in response to the last Office action.

Accordingly, *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the claimed invention*". "The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed* [emphasis added]". Clearly, Applicants do not appear to be in possession of the claimed 'functional variants", or know the required structures required to demonstrate possession of such as currently claimed.

Analogous to the situation decided in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), "an adequate written description of a DNA [product] requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA [product] itself". *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) held that claims directed to mammalian FGFs were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only three structurally unrelated polypeptide species of SEQ ID NOs: 1-3 have been described in the instant specification, which show no common structure.

Accordingly, the court held in *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) that:

"One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is".

and that:

"A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218".

In summary, an invitation for others to discover a representative number of species, in order to reasonably extrapolate to the claimed genus, with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics does not equate to possession of the claimed genus of peptides, because one skilled in the art cannot

reasonably visualize or predict what critical amino acid residues would structurally characterize the genus of polypeptides encompassed by the claims, and for the reasons previously made of record. Thus, the written description requirements under 35 U.S.C. 112, first paragraph are not met. See again MPEP 2163.

7. Claim 38 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the polypeptides of SEQ ID NOs: 1-3 that binds Aβ and inhibit SOD activity and/or copper binding ability, does not reasonably provide enablement for any undefinable "non peptide peptidomimetic". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 20071130 & 20081218, and as follows.

Applicants argue on page 5 of the response how functional variants are described in the specification. In contrast, no guidance on how to make any "non peptide peptidomimetic" is provided within the instant specification, or even argued by Applicants in their response. Therefore, as previously made of record, one of ordinary skill in the art to would not know how to make this claimed invention without requiring undue experimentation to determine such, after-the-fact, and for the reasons previously made of record, which include the specification failing to disclose a single specific amino acid residue or "non peptide" critical for any definable function, including binding to Aβ, for inhibiting copper binding to Aβ, or inhibiting SOD activity. Therefore, consistent with that held by the courts in *In re Wands,* this claim remains not enabled, and for the reasons previously made of record.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes/
Primary Examiner, Art Unit 1649
April 30, 2009